

Mia York

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SUMMARY

Senior pharmacometrics scientist with seven years supporting clinical development through **population PK**, PK/PD, and **exposure response** modeling across early and late stage programs. PhD trained in pharmaceutical sciences with hands on expertise in NONMEM, Monolix, R, **model informed drug development**, clinical trial design, dose regimen evaluation, and regulatory documentation. Converts longitudinal clinical data into clear recommendations for dose selection, study design, and development strategy. Authors analysis plans, pharmacometrics reports, submission materials, and agency responses within SOP controlled environments. Partners closely with clinical pharmacology, statistics, data management, and clinical operations teams, while mentoring junior scientists and improving reproducible workflows. Brings practical scientific judgment, careful **quality control**, and clear communication that can support sound decisions across clinical programs.

EXPERIENCE

Senior Scientist, Pharmacometrics

July 2023 - Present

Northstar Biopharma

Cambridge, MA

Leads population PK, exposure response, and model informed development work across three clinical stage programs. Owns analysis planning, simulation evidence, regulatory documentation, quality control, and mentoring within matrix teams.

- Led **population PK** analyses integrating concentration, efficacy, safety, and covariate data for dose discussions.
- Built **NONMEM** and **R** workflows with diagnostics and visual predictive checks for reproducible review packages.
- Authored **analysis plans** defining datasets, assumptions, sensitivity analyses, QC expectations, and interpretation standards.
- Translated **simulation** results into dose selection options for clinicians, statisticians, and program leaders.
- Supported regulatory modules and agency responses by tracing conclusions to source analyses and technical reviews.
- Mentored junior scientists on model diagnostics, documentation, **software validation**, and controlled workflow improvements.

Scientist II, Clinical Pharmacometrics

June 2021 - June 2023

Lakefront Therapeutics

Chicago, IL

Executed **population PK** and PK/PD analyses for small molecule programs, connecting **modeling** outputs with study planning and regulatory communication. Coordinated traceable datasets, QC, reports, and scientific presentations across development partners.

- Executed population PK and **PK/PD** analyses with NONMEM, Monolix, and R for small molecule programs.
- Developed dosing simulations that informed clinical study planning and special population questions.
- Defined data requirements with **clinical data management** and biostatistics partners before model execution.
- Performed independent QC of models, scripts, tables, figures, and reports against study timelines.
- Drafted **clinical pharmacology** report sections and analyses for regulatory briefing materials and written responses.
- Presented diagnostics and limitations at project meetings and coauthored a peer reviewed PK/PD manuscript.

Scientist, Clinical Pharmacology Modeling

August 2019 - May 2021

Prairie Ridge Pharmaceuticals

Indianapolis, IN

Supported Phase I and Phase II pharmacometric analyses under senior scientific oversight, preparing datasets, models, simulations, and reports that strengthened dose and study design decisions.

- Prepared **modeling** datasets, exploratory graphics, base models, and covariate assessments for Phase I and II studies.
- Applied R and NONMEM to evaluate concentration time data and exposure relationships with reproducible records.
- Generated simulations comparing candidate regimens for escalation, sampling, and subsequent study design discussions.
- Reconciled dosing, sampling, demographic, and laboratory records with programmers and data managers.
- Prepared tables, figures, and report text linking objectives, methods, results, and development conclusions.
- Contributed posters and presentations while following **SOPs**, peer review procedures, and regulatory documentation expectations.

Pharmacometrics Research Fellow

July 2017 - July 2019

Midwest University Medical Center

Milwaukee, WI

Conducted supervised population PK research using clinical and simulated datasets, developing models, simulations, **quality control** routines, and scientific communications for therapeutic development studies.

- Conducted supervised **population PK** research investigating variability and dose exposure relationships in clinical studies.
- Created NONMEM models and R diagnostics comparing structural and statistical assumptions through goodness of fit assessments.
- Designed **simulation** experiments testing dosing questions for faculty investigators and clinical research collaborators.
- Established data cleaning and QC routines for dosing, concentration, and covariate records.
- Prepared methods, results, figures, and technical appendices for abstracts and manuscripts.
- Presented research at scientific meetings and supported trainees with introductory **modeling** and reproducible R practices.

PROJECTS

Clinical Dose Selection Simulation Program 📅 2024

Built a cross functional simulation package that compared candidate dose regimens, summarized exposure response evidence, and supported practical clinical development discussions.

Regulatory Pharmacometric Evidence Package 📅 2023

Connected model assumptions, diagnostics, sensitivity analyses, and interpretation into a traceable package for regulatory documentation and internal decision review.

LEADERSHIP & AWARDS

- Recognized for translating complex pharmacometric findings into clear dose selection recommendations for development teams.
- Selected as a scientific contributor for peer reviewed PK and PD research communications and regulatory support.
- Trusted mentor for junior scientists learning model diagnostics, reproducible R workflows, and controlled documentation.

EDUCATION

Ph.D. in Pharmaceutical Sciences

2017

University of Wisconsin Madison GPA: 4.0

Madison, WI

Coursework: Pharmacometrics, pharmacokinetics, pharmacodynamics, clinical pharmacology

Bachelor's Degree in Biological Sciences

2012

Marquette University GPA: 3.8

Milwaukee, WI

Coursework: Biology, pharmacology, biochemistry, biological research

CERTIFICATIONS

- Good Clinical Practice Training, CITI Program 📅 2026
- Pharmacometric Modeling and Simulation Certificate 📅 2024

TECHNICAL SKILLS

- **Pharmacometrics Software:** NONMEM, Monolix, R
- **Modeling Methods:** Population PK, PK/PD modeling, exposure response modeling
- **Simulation Methods:** Visual predictive checks, dose simulations, sensitivity analysis
- **Clinical Data:** Concentration data, efficacy data, safety data
- **Data Preparation:** Analysis datasets, covariate records, data cleaning
- **Study Development:** Clinical trial design, dose regimen selection, sampling schedules
- **Regulatory Documents:** Pharmacometric reports, agency responses, submission modules
- **Quality Systems:** Quality control, software validation, SOP compliance
- **Scientific Communication:** Scientific presentations, manuscripts, peer review
- **Research Outputs:** Tables, figures, technical appendices

SKILLS

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|---------------------|-------------------------|----------------------|-----------------------|
| • Population PK | • Monolix | • Data Management | • Quality Control |
| • PK/PD Modeling | • R | • Dose Selection | • Software Validation |
| • Exposure Response | • Clinical Pharmacology | • Analysis Plans | • Scientific Research |
| • NONMEM | • Clinical Trials | • Regulatory Writing | |

PROFESSIONAL AFFILIATIONS

- Collaborated with clinical pharmacology, biostatistics, data management, and clinical operations colleagues across matrix programs.
- Shared pharmacometric methods through scientific meetings, internal presentations, manuscripts, and professional research networks.

LANGUAGES

- English (Native)
- Spanish (Intermediate)

ADDITIONAL INFORMATION

Work Status : Authorized to work in United States. No sponsorship required.

REFERENCES

AVAILABLE ON REQUEST